



StrongSchoolsNC

K-12 COVID-19 Antigen Testing Interim Guidance

March 4, 2020



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**



What's Inside

Interim Guidance For COVID-19 Testing of Adults and Children Who Work at or Attend a K-12 School	3
Types of Covid-19 Tests	3
Testing Strategies	4
Background on COVID-19 Antigen Testing in NC Public Schools	5
Operational Guidance for Opt-In COVID-19 Antigen Testing in NC Public Schools.....	7
Test Request and Distribution Process	7
Requirements to Request Abbott BinaxNOW Antigen Test Kits	8
<i>Obtain a CLIA Certificate</i>	<i>8</i>
<i>Secure a Signed Physician Order.....</i>	<i>8</i>
<i>Ensure All Staff Complete Training Requirements.....</i>	<i>9</i>
<i>Obtain Consent from Parents/Guardians and Notifications Around Testing</i>	<i>9</i>
<i>Verify Ability to Complete all Reporting Requirements</i>	<i>9</i>
<i>Maintain an Adequate Supply of PPE</i>	<i>10</i>
<i>Disposal of Medical Waste</i>	<i>10</i>
<i>Plan for Safe Isolation and Quarantine</i>	<i>11</i>
Readiness Review Checklist for Public Schools.....	12
Frequently Asked Questions on K-12 Testing Request Process.....	13

Interim Guidance For COVID-19 Testing of Adults and Children Who Work at or Attend a K-12 School

Families of students, school administrators, staff, and local health leaders are working together as schools continue to operate in-person across the state to mitigate the spread of COVID-19. K – 12 schools have implemented thoughtful, detailed protocols to prevent and respond to potential cases of the virus among their students and staff in alignment with the StrongSchoolsNC public health guidance.

As ample supply of COVID tests are available across the state, we know that local partners have questions about the use of COVID-19 testing in education settings and/or among adults and children who work at or attend a K-12 school. This is an emerging area of public health practice and there is currently limited scientific or evidenced- based data on effective and efficient testing protocols and strategies.

As more public health research evolves and more is learned, NCDHHS will continue to update this guidance as a reference for Local Education Agencies (LEAs) - including independent, public, and charter schools, in consultation with their Local Health Departments (LHDs) to determine their own local approaches to administering COVID-19 tests, at their discretion.

Types of Covid-19 Tests

There are two main types of viral tests that can be used to diagnose someone with COVID-19 (diagnostic tests):

- **Polymerase chain reaction (PCR)/molecular** tests detect the virus’s genetic material. This test is the “gold standard” for detecting the virus that causes COVID-19 and typically requires a sample being sent to a laboratory. For this test, it is most common that samples are collected through a nasal or throat swab.
- **Rapid antigen** tests, which detect protein on the surface of the virus, are less sensitive and less specific than the PCR/molecular test. This means they miss some infections that would be detected by a PCR/molecular test, and they may be positive in someone who does not actually have the infection. In addition, more is known about their accuracy in people with symptoms than in people without symptoms. However, they can be performed without having to send the sample to a laboratory and results come back quickly (e.g., approximately 15 minutes). For this test, a sample may be collected through a nasal swab.
 - Rapid antigen tests sometimes need to be followed up and verified with PCR/molecular testing. For a diagram explaining more on the use, interpretation and expected response steps for COVID-19 antigen tests, see this link: <https://files.nc.gov/covid/documents/guidance/healthcare/NCDHHS-Antigen-Flowchart.pdf>

Testing Strategies

The CDC released its K-12 School Operational Strategy on February 12th, 2021, which encourages testing as an additional layer of prevention in schools. The [Centers for Disease Control and Prevention recommends](#) diagnostic and screening testing as an **additional** prevention measure in addition to the essential mitigation strategies of mask use and physical distancing, among others. Testing is not required for schools to provide in-person instruction.

The K-12 testing strategies recommended by the CDC and supported by NC DHHS are:

- **Diagnostic testing** for individuals who exhibit symptoms of COVID-19 at school or have recent known close contact to a person with COVID-19
- **Screening testing** for K-12 staff (adults) on a regular, routine basis (e.g., weekly) -

Testing should be combined with other key mitigation strategies, such as NC's StrongSchools requirements: universal mask use, physical distancing, handwashing and maintaining healthy and clean facilities.

For more details about K-12 COVID-19 testing guidance, refer to the most up-to-date [CDC recommendations](#).

For detailed steps for schools and local health leaders on responding to positive diagnostic or screening tests, refer to the NCDHHS [Reference Guide for Suspected, Presumptive, or Confirmed Cases of COVID-19 \(K-12\)](#).

For additional guidance on how to safely reopen schools, please see the [NC Strong Schools Public Health Toolkit](#).

Background on COVID-19 Antigen Testing in NC Public Schools

Abbott BinaxNow Antigen Tests

In the fall, the US Department of Health and Human Services procured and distributed to states Abbott BinaxNOW COVID-19 tests



- Designed for rapid diagnosis of active infections within 5-7 days of symptom onset
- Generally, less sensitive than PCR tests (greater chance of false negatives).
- Tests can be performed by anyone who has undergone a training from BinaxNOW. Testing personnel do not need to be a healthcare professional. Testing personnel must collect and report patient and result information properly.
- Tests must be performed at a location that has a CLIA certificate of waiver and meet CLIA regulatory requirements

NC DHHS K-12 Antigen Testing Pilot

NC DHHS used a portion of these free tests to conduct a pilot of COVID-19 testing in K-12 schools

- From Dec 2020 to Feb 2021, 53,000 free tests were sent to 17 schools districts and 11 charter schools to conduct testing at over 200 schools
- 3 check-in meetings along with a pre- and post- survey were used to support participants and gather qualitative and quantitative data about participating schools' experience

Key takeaways from the pilot included:

- Schools that added mitigation layer of tests improved the confidence in and ability for staff, families and students coming back to schools.
- Families and staff feel more supported, as school-based testing improves access to those who may not be able to afford or find a timely community testing option.

- We've also heard that some of the operational components, especially reporting tests, can be a challenge. In response: DHHS will be providing weekly trainings on our reporting process and office hours to help schools work through these challenges.
- Prior to implementing a testing strategy, a LEA/school should consider the staffing and communication infrastructure needed to support testing and follow up in the school setting, such as layout of facilities for conducting testing (whether on-site at the school or in partnership with another testing location), having enough trained staff to administer and interpret test results, and school community (students, staff, families) buy-in to the screening testing approach.

As LEAs and charter schools thinking about developing a testing program of their own may consider consulting with a district and/or school that participated in the pilot in order to learn directly from a peer. Please see the list of all pilot participants below.

K12 Antigen Testing Pilot Participants:

- Alamance County: Alamance-Burlington School System (33 locations)
- Bladen County: Emereau Bladen Charter School (1 location)
- Buncombe County: Asheville City Schools (11 locations), Buncombe County Schools (44 locations), Francine Delany Charter School (1 location)
- Cabarrus County: Cabarrus Charter K-12 (2 locations), Cabarrus County Schools (6 locations), Kannapolis City Schools (2 locations)
- Catawba County: Catawba County Schools (29 locations), Hickory Public Schools (9 locations), Newton Conover City Schools (6 locations)
- Durham County: Central Park School for Children (1 location), Healthy Start Academy (1 location)
- Forsyth County: NC Leadership Academy (1 location)
- Gaston County: Gaston County Schools (1 location)
- Harnett County: Harnett County Schools (28 locations)
- Johnston County: Johnston County Public Schools (1 location)
- Lenoir County: Lenoir County Public Schools (17 locations)
- Lincoln County: Lincoln Charter School (2 locations)
- Madison County: Madison County K-12 Public Schools (6 locations)
- Mecklenburg County: Lake Norman Charter (1 location), Sugar Creek Charter School (1 location), UpROAR Leadership Academy (1 location)
- Pasquotank County : Northeast Academy for Aerospace and Advanced Technologies (1 location)
- Surry County: Elkin City Schools (3 locations), Mount Airy City Schools (4 locations), Surry County Schools (20 locations)
- Wilson County: Wilson County Schools (2 locations)

Operational Guidance for Opt-In COVID-19 Antigen Testing in NC Public Schools

The North Carolina Department of Health and Human Services will be expanding access to COVID-19 rapid testing in K-12 public schools to add further protection for students, school staff and teachers, on an opt-in basis. When schools implement testing combined with the state's strong mitigation strategies, they can detect new cases to prevent outbreaks, reduce the risk of further transmission, and protect students, teachers, and staff from COVID-19.

Tests will be available at no cost for all Local Education Agencies (LEAs) and charter schools to opt-in to conduct diagnostic testing of students and staff and/or screening of adult staff.

LEAs and charter schools may choose to request tests for any of the options below:

1. Testing all individuals, including students, their families and school staff, who are symptomatic or had known exposure to a confirmed positive case, and/or
2. Once weekly screening of all adults – including teachers and staff

All LEAs/ charter schools interested in providing any testing must meet certain requirements. Once the interested LEA or charter school has a plan in place to meet all requirements, they are eligible to submit a request to NC DHHS via an [online form](#).

Test Request and Distribution Process

An LEA or charter school interested in receiving tests for diagnostic or screening testing from NCDHHS must:

1. Review the [readiness checklist](#) and define a plan to meet requirements
Interested LEAs must communicate with schools in their district to identify interested schools and submit one (1) request
2. Send completed checklist to the local health department (LHD) to inform them of intention to conduct testing
Formal LHD approval or sign-off is not required to perform tests
3. Complete the NC DHHS [antigen test request form](#)
We encourage LEAs/ Charter schools to include an LHD point-of contact and contact information, so the LHD may be informed of LEA/ charter schools request status

NC DHHS will review requests twice weekly and communicate request status to requestor and LHD point of contact (if provided) within 3-5 days of request submission. Shipment tracking information for approved requests will be sent to shipping point-of-contact provided in the request form. LEAs or charter schools may request additional tests via the same request form above as existing supply is used and reported to public health.

Requirements to Request Abbott BinaxNOW Antigen Test Kits

All LEAs and Charter Schools interested in conducting ANY testing must complete all eight (8) of the following requirements in order to receive approval from DHHS for their distribution of Abbott BinaxNOW antigen test kits.

1. **CLIA Certificate** – [Obtain an approved CLIA certificate](#) or partner with an entity with a CLIA certificate
2. **Physician Order** – Secure a signed physician order for testing or elect to use the [Statewide Order](#)
3. **Training** – Ensure all testing personnel have completed [training modules](#)
4. **Parent / Guardian consent** – Obtain consent prior to testing students and notify parents/guardians when testing has been performed
5. **Reporting** – Verify ability to complete [DHHS reporting requirements](#)
6. **PPE** – Maintain an [adequate supply](#) of PPE to perform tests
7. **Medical Waste** – Adhere to standards to properly handle and dispose of [medical waste](#)
8. **Plan for Safe Isolation and Quarantine** – We encourage schools to closely consider additional support needs for historically marginalized or vulnerable groups

LEAs / charter schools can choose to meet these requirements **independently or partner** with a provider, laboratory or other similar organization.

More detailed information about each requirement is provided below. Test requestors should also consult the list of Frequently Asked Questions at the end of this document for more information about how a requirement may be met.

Obtain a CLIA Certificate

The [FDA Emergency Use Authorization for BinaxNOW](#) supports testing in point-of-care settings operating under a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Any site that performs laboratory testing must follow applicable regulatory requirements including federal, state, and local mandates for testing, as well as requirements for the safety and confidentiality of personal information. Use of this authorized test is limited to CLIA certified entities.

An LEA or charter school may choose to apply or utilize its own CLIA certificate or partner with an entity that has a CLIA certificate that can be extended to include the district or school. Additional details on obtaining a CLIA certificate can be found in the FAQs in this document and on the NC Division of Health Service Regulation (DHSR) CLIA [website](#).

Secure a Signed Physician Order

The Abbott BinaxNOW test must be ordered by a healthcare professional. North Carolina has a statewide [standing order](#) which authorizes individuals to obtain a SARS-CoV-2 diagnostic test at a testing site. The site may use this standing order, or sites may consider obtaining a standing Interim Guidance For COVID-19 Testing of Adults and Children Who Work at or Attend a K-12 School – March 4, 2021

order from another provider, including a school physician or a local health department medical director.

Ensure All Staff Complete Training Requirements

All staff administering Abbott BinaxNOW test kits within a school or district must complete all Abbott BinaxNOW training modules available [here](#). These modules provide a detailed step-by-step guide to the test process. All the modules should be completed in their entirety prior to staff performing tests on individuals.

Test administrators do not need to be medical professionals. It is the responsibility of the entity holding the CLIA certificate of waiver (i.e., district, school, or CLIA-certified partner) to ensure that all the staff administering tests have completed the necessary training requirements. NC DHHS recommends that sites host a training for all staff that will be administering tests, to complete the manufacturer modules collectively, ask questions and share other critical protocols, such as PPE donning/doffing.

Obtain Consent from Parents/Guardians and Notifications Around Testing

Sites administering Abbott BinaxNOW tests kits must establish consent and notification processes for all parents/guardians prior to beginning testing. Once sites have begun administering Abbott BinaxNOW test kits, they must obtain parental/guardian consent before performing a test on a student. LEAs or charter schools are responsible for developing the required consent forms.

Sites must also notify parents/guardians when a student has received an Abbott BinaxNOW test while at school, the result of the test, and next steps they must take to ensure follow-up, dependent on the child's test results. Sample communications to parents/guardians regarding positive test results can be found in [Contact Tracing Procedures for K-12 Schools](#). We encourage interested sites to review this guidance in full, to inform their communications to parents/guardians and staff regarding contact tracing and case investigation procedures and how schools can effectively partner with their local health department in contact tracing. Additional information on these processes can be found in the [Reference Guide for Suspected, Presumptive, or Confirmed Cases of COVID-19 \(K-12\)](#).

Verify Ability to Complete all Reporting Requirements

All positive and negative test results must be reported daily as part of required reporting of COVID-19 diagnostic tests. The most current reporting requirements and methods of reporting of COVID-19 diagnostic tests are described in the [NC Administrative Code Emergency Rule](#) and the [associated NCDHHS guidance for reporting results](#).

If capabilities exist within the LEA, charter school or their partner organization to submit results electronically, we encourage sites to do so. Options for electronic reporting can be found at [Getting Started with Automated Reporting: NC DHHS COVID-19](#). Choices best suited for education facilities are the [COVID-19 Laboratory Data Automation \(“CLDA”\) process](#) or an online tool, [eCATR Patient Test Results \(PTR\)](#). You DO NOT need to be or work with a laboratory to submit results through the eCATR PTR tool, as long as you or your partner organization have received a CLIA certificate of waiver. Please allow 3-5 business days for your registration to be approved.

To support interested LEAs and charter schools new to reporting COVID-19 test reports, NC DHHS will be hosting 1-hour weekly trainings on Wednesdays at 1PM starting March, open to all individuals who will be responsible for performing and/or reporting tests. NC DHHS encourages sites to explore options to engage non-clinical personnel in reporting process, to allow clinical personnel to focus on overseeing testing efforts. Individuals interested in attending this training should email StrongSchoolsNC@dhhs.nc.gov to be added to the invitation.

Maintain an Adequate Supply of PPE

All staff administering Abbott BinaxNOW test kits must wear appropriate personal protection equipment when running each test and handling patient specimens. For personnel collecting specimens or within 6 feet of individuals suspected to have COVID-19, the following PPE is required:

- A surgical or procedural mask (a fit-tested N95 or higher level respirator can be used if available)
- Eye protection
- Gloves
- Gown, when collecting specimens

Sites must be able to maintain an adequate supply of PPE as is required to administer tests. Please see NC DHHS’s website for [information on requesting PPE](#) from the state if needed.

Disposal of Medical Waste

All components of the BinaxNOW test kit, as well as gloves used by personnel administering the tests and any grossly contaminated PPE, should be discarded as biohazard waste according to federal, state, and local regulatory requirements. Sites administering tests must have a means to appropriately package, transport, and dispose of medical waste. Expired tests should also be exposed of as medical waste. Please pay close attention to the expiration dates listed on test packaging.

If your LEA or schools do not already have medical waste disposal processes in place, many sites participating in the pilot partnered with vendors such as SteriCycle to provide this service.

Plan for Safe Isolation and Quarantine

Some students, parents and staff may be disproportionately impacted by quarantine and isolation requirements after testing. As districts and schools have throughout the COVID 19 response, we advise sites to continue to consider the financial, emotional and educational tolls incurred by the populations that they serve and have a toolkit ready to support these individuals. NCDHHS has put together guidance and resources for schools and parents related to [remote learning](#), [food assistance](#), [internet access](#), [child care](#), and [other support services](#) that we encourage sites to leverage in developing their plans.

NC DHHS will provide the following resources to support interested LEAs/ Charter Schools:

- Weekly office hours to answer questions from interested or enrolled sites
- Weekly DHHS-hosted training sessions on test results reporting platform, *eCATR PTR*
- StrongSchoolsNC@dhhs.nc.gov for ongoing questions and support

General Office Hours: To support LEAs and charter schools in successfully implementing a testing and screening program, NC DHHS will be holding weekly **office hours on Fridays from 9:30-10:30AM** to address any questions and provide guidance on topics regularly escalated by sites. Sites that submit a request to receive tests will automatically be provided with information on how to join these calls. If your LEA or charter school is in the planning phases and not yet ready to submit a request, but would like to join office hours, please email our team at StrongSchoolsNC@dhhs.nc.gov to request to be added to the call.

Reporting Trainings: To support interested LEAs and charter schools new to reporting COVID-19 test reports, NC DHHS will be hosting 1-hour weekly trainings on Wednesdays at 1PM starting March 10th, open to all individuals who will be responsible for performing and/or reporting tests. NC DHHS encourages sites to explore options to engage non-clinical personnel in reporting process, to allow clinical personnel to focus on overseeing testing efforts. Individuals interested in attending this training should email StrongSchoolsNC@dhhs.nc.gov to be added to the invitation.

Readiness Review Checklist for Public Schools

LEAs or charter schools interested in conducting diagnostic and/or screening testing using the free, opt-in test request process must review, complete, and send this checklist to their local health department to inform them of the LEA / charter schools' intention to test and that they can meet all requirements themselves, or by collaborating with a partner organization.

Please direct questions to StrongSchoolsNC@dhhs.nc.gov.

- ☐ **CLIA Certificate of Waiver:** The site has received a CLIA Certificate of Waiver OR has identified an entity with a CLIA Certificate to perform tests.
- ☐ **Physician Order:** The site has acquired a signed standing order for COVID-19 testing with the Abbott BinaxNOW from a physician or has elected to use the statewide standing order.
- ☐ **PPE:** The site has acquired an adequate supply of PPE and will be able to procure additional PPE as is needed. Additionally, the appropriate staff that will be administering the Abbott BinaxNOW test have reviewed [CDC guidance](#) on the use of PPE.
- ☐ **Training Requirements:** The site has ensured that all personnel administering Abbott BinaxNOW test kits have completed all necessary training modules.
- ☐ **Consent and Notification Processes:** The site has identified consent and notification processes for all parents/guardians prior to beginning testing with any students.
- ☐ **Reporting Requirements:** The site has trained all necessary staff on how to appropriately report test results daily to state or local public health.
- ☐ **Medical Waste:** The site has a mechanism to safely dispose of used testing material.
- ☐ **Plan for Safe Isolation and Quarantine:** The site has a plan in place to provide additional support needs for historically marginalized or vulnerable groups.
- ☐ **Ongoing Requirements:** The site will adhere to the following ongoing requirements:
 - Testing personnel will adhere to the written Instructions for Use (IFU) provided by the manufacturer in the test package insert.
 - Ensure NC DHHS has up-to-date information on test administrators and locations.
 - Abide by the infectious waste disposal criteria.
 - Acquire consent for all individuals being tested, or his/her parent/guardian.
 - Submit all required data elements to DHHS at least every 24 hours.
 - Retain documentation related to the testing program for at least 2 years.
 - Cooperate with their LHD on contact tracing as advised in the [StrongSchoolsNC Public Health Toolkit](#) and consider developing a contact tracing plan as advised in the [StrongSchoolsNC COVID-16 Contact Tracing Procedures for K-12 Schools](#).
 - Review and stay up-to-date on the CDC's [recommendations for K – 12 testing](#).

Frequently Asked Questions on K-12 Testing Request Process

Contents

Q1: If we already have a CLIA waiver for schools to conduct other testing, do we need another for antigen testing?	14
Q2: How can a site obtain a CLIA certificate of waiver?	14
Q3: Does a site need a medical order to perform these tests?	15
Q4: What training is required to administer these tests? Do the tests require a medical professional to administer them?.....	15
Q5: Who is eligible for testing at a site?	16
Q6: For diagnostic testing, if a student or staff is symptomatic or is an asymptomatic close contact, should they come to school to get tested?	16
Q7: Is parental/guardian consent required to administer a COVID-19 test to a child?	16
Q8: Is a sample student consent form available to share?.....	16
Q9: What happens after a positive or negative Abbott BinaxNOW rapid antigen test?.....	17
Q10: Who is responsible for following up with the student or staff member after test results, and contact tracing (if applicable for a positive test)?	18
Q11: Can tests be used to test school staff members on day 5 of quarantine so that they may return to work?	18
Q12: What are the requirements around the storage or disposal of the Abbott BinaxNOW tests?	18
Q13: What are the requirements around PPE with the Abbott BinaxNOW tests?	19
Q14: Does NC DHHS require or recommend a COVID case dashboard on the school website, so stakeholders are aware?	19
Q15: Are the at-home test kits the same as the tests NC DHHS is providing to schools?	19
Q16: How can I contact Abbott directly with any additional questions?	19

If you have questions about any information contained in this document that cannot be answered by the [FAQ](#), please contact StrongSchoolsNC@dhhs.nc.gov.

Q1: If we already have a CLIA certificate of waiver for schools to conduct other testing, do we need another for antigen testing?

A: You do not need a new CLIA certificate of waiver; however, you do need to modify your existing certificate of waiver to include the Abbott BinaxNOW antigen test. The [CMS form 116](#) should be used to report any change of information on the current CLIA certificate. If you have any questions, please contact DHSR at DHSR.CLIA@dhhs.nc.gov or via phone at (919) 815-4620.

Q2: How can a site obtain a CLIA certificate of waiver?

A: The [FDA Emergency Use Authorization for BinaxNOW](#) supports testing in point-of-care settings operating under a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Any site that performs laboratory testing, including antigen testing, must follow applicable regulatory requirements including federal, state and local mandates for testing, as well as requirements for the safety and confidentiality of personal information. Use of this authorized test is limited to CLIA certified entities. The application for a CLIA Certificate (CMS Form 116) can be found here: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>

If applicable, an LEA / charter school may apply for one CLIA Certificate of Waiver that would include all schools in the district. For your convenience, we are sharing some information that may help you fill out your CLIA application if your facility does not already have one:

- In section I, select “Other Changes (Specify)” and fill in “COVID 19” to alert our program that your application is a part of this distribution effort.
- In section II, select “Certificate of Waiver”.
- In section III, select “26-School/Student Health Service”.
- In section V, select “Yes” if you are applying as a school district and have more than one school in your district.
 - In #1 in section V, select “No” as each school may act as a temporary testing location should there be a need to test students, teachers, or staff.
 - In #2 – “Yes,” and #3, “No”
- In section V, select “No. If no, go to section V1” if you are applying as a school at a single site.
- In section VI, enter “BinaxNOW COVID-19 Ag Card”
- Completely fill out the other sections, as applicable.

Please also include information about other medical tests, including any other COVID-19 tests, you may be performing at this location and provide specifics on these test systems. Please send the completed application to NCDHHS Division of Health Service Regulation/CLIA Certification at DHSR.CLIA@dhhs.nc.gov or via fax to (919)733-0176. If you have any questions, please contact DHSR at (919) 815-4620.

Q3: Does a site need a medical order to perform these tests?

A: Yes, the Abbott BinaxNOW rapid antigen tests must be ordered by a healthcare professional. North Carolina has a statewide [standing order](#) which authorizes individuals to obtain a SARS-CoV-2 diagnostic test at a testing site. The pilot site may use this standing order, or pilot sites may consider obtaining a standing order from another provider, e.g., a school physician or local board of health medical director.

Q4: What training is required to administer these tests? Do the tests require a medical professional to administer them?

A: No, test administrators do not need to be medical professionals. The Emergency Use Authorization (EUA) received by the Abbott BinaxNOW rapid antigen test allows it to be performed by a person who receives a specific training, described below.

All staff administering Abbott BinaxNOW test kits at a site must complete all Abbott BinaxNOW training modules. The Abbott BinaxNOW training modules can be found [here](#) and are listed below:

- Module 1: Getting Started
- Module 2: Quality Control
- Module 3: Specimen Collection and Handling
- Module 4: Patient (Individual) Test
- Module 5: Navica Admin App

These modules provide a detailed step-by-step guide to the test process. All the modules should be completed in their entirety prior to staff performing test on individuals.

Further information about the proper use of the Abbott BinaxNOW test kits can be found on the package insert and [here](#). This includes information regarding specimen collection, handling, transportation, and storage.

It is the responsibility of the entity holding the CLIA certificate of waiver (i.e., district, school, or CLIA-certified partner) to ensure that all the staff administering tests have completed the necessary training requirements.

Documentation or records of satisfactory completion of training should be maintained by the school, district or partner organization performing tests.

Staff who have questions or concerns about the administration of the test can always utilize these direct links to Abbott support: 800-257-9525 8:00 am – 8:00 pm Monday through Friday or ts.scr@abbott.com

Q5: Who is eligible for testing at a site?

A: Public or charter school students and staff at sites who have symptoms of an illness consistent with COVID-19 or are close contacts with someone with COVID-19 (based on the [CDC definition of close contacts](#)) can be tested using the Abbott BinaxNOW antigen test. LEAs and Charter schools may also choose to test family members of students, if they are present and also experiencing symptoms or had a close contact.

LEAs or charter schools may also choose to conduct routine screening testing of adults. Routine screening should include adults without symptoms or suspicion of exposure. LEAs or charter schools are at their discretion to determine the eligible adult population to include in screening. NC DHHS recommends once weekly screening of ALL adults interacting with students or within the school setting, including substitute teachers, bus drivers, food service and custodial staff.

Q6: For diagnostic testing, if a student or staff is symptomatic or is an asymptomatic close contact, should they come to school to get tested?

A: NC DHHS encourages all sites to adhere to the state's isolation and [quarantine guidance](#) for individuals that are ill or had a known exposure and recommends these individuals be referred to their provider or another [off-site setting](#) rather than coming on-site for testing. If these options are not available or accessible to the individual and the school or partner organization is conducting drive thru or non-school based testing, they may choose to allow symptomatic or close contact individuals to come to be tested to support response and mitigation efforts, such as contact tracing and case investigation. However, the individual should otherwise continue to follow quarantine and isolation guidance.

Q7: Is parental/guardian consent required to administer a COVID-19 test to a child?

A: Yes. Sites administering Abbott BinaxNOW tests kits must identify consent and notification processes for all parents/guardians prior to beginning testing and must obtain parental/guardian consent before performing a test on a student.

Additionally, schools and districts must send notification forms to inform parents/guardians when a student has received an Abbott BinaxNOW test while at school and the result of the test. The notification form also serves to inform parents/guardians on what next steps they must take to ensure follow-up, dependent on the child's test results.

Q8: Is a sample student consent form available to share?

A: There is no single statewide consent form. NC DHHS advises LEAs or charter schools to work with their legal teams to develop a form and define a process for obtaining required consent.

Q9: What happens after a positive or negative Abbott BinaxNOW rapid antigen test?

A: See the information below, as well as referring to the [DHHS flowchart on using and interpreting antigen test results](#).

Positive Test:

Any individual experiencing COVID-19 symptoms for 7 days or less who tests positive, should be treated as a positive COVID-19 case and managed accordingly (see DHHS protocol for responding to COVID-19 scenarios [here](#)).

Any positive antigen test result in an individual who does not have symptoms of an illness consistent with COVID-19 or known exposure to someone with COVID-19 should be confirmed with a PCR test in a CLIA-certified laboratory. The person who received a positive antigen test result should be isolated while awaiting confirmatory test results.

Negative Test:

No further follow-up is required for a negative antigen test result in an individual who does **not** have COVID-19 symptoms or known exposure to someone with COVID-19.

If an individual with symptoms of an illness consistent with COVID-19 according to [DHHS screening guidance](#) has a negative test, they should be sent home. The parent/guardian should be informed that the negative test is presumptive, and they should follow up with [another testing site](#) or their healthcare provider for a confirmatory PCR test for COVID-19. The student may return to school after they have 1) obtained a subsequent negative PCR test for COVID-19, have an improvement in symptoms, and have been without fever for at least 24 hours without the use of fever reducing medications; **or** 2) have been removed from school for 10 days from the start of symptoms, as long as their symptoms have improved and they have been without fever for at least 24 hours prior to their return to school without the use of fever reducing medication.

If an individual with mild symptoms not included in the screening checklist (e.g., isolated runny nose, sore throat, abdominal pain without fever) tests negative, they may return to school. A communication should be sent to the parent/guardian informing them of the result. The parent/guardian should be instructed to monitor the child carefully for fever and other symptoms and if these develop, to refer to the child's healthcare provider. A follow-up PCR test may be indicated.

Communication to Parent/Guardian

After every test, positive or negative, communication should be sent to the parent/guardian informing them of the result.

Q10: Who is responsible for following up with the student or staff member after test results, and contact tracing (if applicable for a positive test)?

A: Case investigation and contact tracing should be done as a collaboration between K-12 schools and local health departments. [Guidance for coordinating contact tracing efforts](#) with schools and local health departments is available on the NCDHHS website. It is imperative that schools and districts collaborate with the local health department in providing contact information for, or notifying close contacts of, a suspected or confirmed COVID-19 case among staff, students, and families while maintaining confidentiality.

Additionally, schools and districts should appropriately exclude students and faculty/staff from school during isolation and quarantine, and advise staff, students, and parents to be aware of the possibility of calls from contact tracers from the local health department. Additional steps that schools and districts can do to enhance current practices to increase the speed and efficiency of contact tracing in collaboration with the health department, including developing a contact tracing plan, is found in the Guidance linked above.

Q11. Can tests be used to test school staff members or students on day 5 of quarantine so that they may return to school?

A: CDC recommends that people be in quarantine for 14 days after an exposure to someone with COVID-19; however, they recently revised their guidance to include options for shortened quarantine in some situations. This could include ending quarantine after day 7 if a test is performed on day 5 or later and is negative (see [CDC website for guidance](#)) and the individual is without symptoms of COVID. It is at the discretion of the local health department whether they would like to implement this strategy locally. Please check with your LHD. According to the CDC guidance, antigen tests can be used for the purpose of ending quarantine. They are not as sensitive at detecting virus as PCR tests but using tests on day 5 or later would still be consistent with CDC guidance.

Q12: What are the requirements around the storage or disposal of the Abbott BinaxNOW tests?

A: All staff administering the tests must follow the instructions provided on the Abbott BinaxNOW package insert regarding specimen collection, handling, transport and storage as is detailed here: <https://www.fda.gov/media/141570/download>. All components of this kit should be discarded as biohazard waste according to federal, state and local regulatory requirements.

Though testing outdoors may be ideal for social distancing and ventilation purposes, it also poses a number of challenges, temperature being one. All test components should be at room temperature before use, defined as 15-30°C (59 - 86°F). We therefore recommend indoor

testing if temperatures fall outside of that range. We recognize that indoor testing may not be feasible or safe in all settings; in those circumstances, assure testing supplies are maintained within the defined range and consider use of temperature control equipment outside.

Q13: What are the requirements around PPE with the Abbott BinaxNOW tests?

A: All staff should follow standard precautions when running each test and handling clinical specimens. For personnel collecting specimens or within 6 feet of individuals suspected to have COVID-19, the following PPE is required:

- A surgical or procedural mask (a fit-tested N95 or higher-level respirator can be used if available)
- Eye protection
- Gloves
- Gown, when collecting specimens

Staff administering tests must change gloves between handling of specimens suspected of COVID-19. Additionally, when using patient swabs, minimize contamination of the swab stick and wrapper by widely opening the wrapper prior to placing the swab back into the wrapper. Visit the [CDC website for PPE guidance](#) or contact your local health department for further information regarding the proper use of PPE. Schools and districts must be able to maintain an adequate supply of PPE as is required to administer tests as needed.

Q14: Does NC DHHS require or recommend a COVID case dashboard on the school website, so stakeholders are aware?

A: NCDHHS is not requiring that schools publish a COVID case dashboard. Dashboards can provide helpful information to families and the public and be effective in managing incoming emails and calls to the school; however, regular dashboards do require maintenance and consistent effort. For example, one pilot district indicated that their dashboard works in unison with contact tracing and increases transparency but is demanding to keep up-to-date.

Q15: Are the at-home test kits the same as the tests NC DHHS is providing to schools?

A: No, they are not the same test. Tests distributed to sites by NCDHHS require a CLIA certificate of waiver and trained personnel to administer.

Q16: How can I contact Abbott directly with any additional questions?

A: Abbott customer support can be contacted at 800-257-9525 from 8:00 am – 8:00 pm Monday through Friday, or via email at ts.scr@abbott.com